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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,587	01/31/2002	Harvey D. Preisler	047940-0135	1948

23524 7590 04/21/2005

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/062,587	Applicant(s) PREISLER, HARVEY D.	
	Examiner Karen A. Canella	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-31 and 33-54 is/are pending in the application.
 4a) Of the above claim(s) 24-31,34-38,46-51 and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3-21 and 33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1, 18-22, 26, 27, 30, 31, 33, 39, 43 and 49 have been amended. Claims 2, 23, and 32 have been canceled. Claims 52-54 have been added. Claims 1, 3-22, 23-31, 33-54 are pending. Claims 24-31, 34-38, 46-51 and 54, remain withdrawn from consideration. Claims 1, 3-21, 33, 39-45, 52 and 53 are under consideration.

Applicant requests rejoinder of the instant product claims to the method claims. This will be done for method claims limited to the scope of the product claims at the time that all the product claims are found to be allowable.

Applicant argues that the instant application be given the effective filing date of the provisional application, 60/278,465. This has been considered but not found persuasive. One of skill in the art, upon reading of the '248 application would not have deduced that the undue of peptides disclosed in the instant application were part of the claimed invention because there is no nexus between the structure of the peptides of SEQ ID NO:1-6 and the additional peptide disclosed by the instant application, SEQ ID NO:7-23, and 26-31.

Claims 52 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52 recites wherein the one or more conservative amino acid substitutions do not decrease the biological activity of the isolated polypeptide as compared to the non-conservative amino acid substituted polypeptide from which a substituted polypeptide derives. It is noted that "substituted polypeptide" lacks antecedent basis within the claim, and it is unclear how "substituted polypeptide" relates to the isolated polypeptide having one or more conservative amino acid substitutions.

It is unclear how claim 53 further modifies claim 52 because the specification does not provide a definition of "consisting essentially of" that would differentiate the claimed polypeptides from those "comprising" sequence selected from A or B.

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Claims 39-45, 52 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(A)As drawn to new matter

Claim 39 has been amended to recite the negative limitation that the peptide does not bind to a tumor-specific antigen. The specification discloses the peptide sequence of SEQ ID NO:1-23 and 26-31 that were obtained by screening phage display peptides libraries for binding to leukemic cells versus normal lymphocytes. While the specification states that the disclosed method provides a means for binding to cell surface structures that are not highly immunogenic, there is no teachings in the specification which would exclude peptides identified in the screen which would bind to tumor antigens. It is noted that the binding partners for SEQ ID NO:1-23 and 26-31 were not identified by the specification, therefore the specification and claims as filed do not provide support for this limitation.

(B)As drawn to inadequate written description

New claims 52 and 53 are drawn in part to a genus of proteins comprising one or more conservative amino acid substitutions in each of SEQ ID NO:1-23 and 26-31 wherein the one or more conservative amino acid substitutions do not decrease the biological activity of the isolated polypeptide as compared to the non-conservative amino acid substituted polypeptide from which a substituted polypeptide derives.

The genus of conservative variants is itself highly variant because the genus tolerates numerous structural differences from the disclosed SEQ ID NO:1-23 and 26-31 as well as differences in function from SEQ ID NO:1-23 and 26-31. It is noted that the limitation of not decreasing the biological activity relative to a non-conservative substitution does not describe the function of the polypeptides encompassed by the claims because particular biological activities of each of SEQ ID NO:1-23 and 26-31, apart from the simple binding to cells, have not been disclosed.

Claims 52 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by.

- a. Database Caplus on STN, Accession Number 2001:624615, Shimkets et al (WO 01/47944) discloses a protein sequence comprising a conservative variant of SEQ ID NO:2 as indicated by the underlined area,
- b. Database Caplus on STN, Accession Number 2000:384488, Pelletier et al (WO 00/32835) disclose a protein sequence comprising a conservative variant of SEQ ID NO:1 as indicated by the underlined area,
- c. Database Caplus on STN, Accession Number 2000:384548, Ruvkun et al (WO 00/33068) discloses a protein sequence comprising a conservative variant of SEQ ID NO:3 as indicated by the underlined area,
- d. Database Caplus on STN, Accession Number 2000:260339, Panayi et al (WO 00/21995) discloses a protein sequence comprising a conservative variant of SEQ ID NO:4 as indicated by the underlined area,
- e. Database Caplus on STN, Accession Number 1995:471011, Coombs et al (Bioorganic and Medicinal Chemistry Letters, 1995, Vol. 5 pp. 611-614) discloses a protein sequence comprising a conservative variant of SEQ ID NO:5 as indicated by the underlined area,
- f. Database Caplus on STN, Accession Number 1999:691218, Arigoni et al (WO 99/54473) discloses a protein sequence comprising a conservative variant of SEQ ID NO:6 as indicated by the underlined area,
- g. Database Caplus on STN, Accession Number 2000:9190, Mayer et al (Nature 1999, Vol. 402, pp. 769-777) discloses a protein sequence comprising a conservative variant of SEQ ID NO:13 as indicated by the underlined area,
- h. Database Caplus on STN, Accession Number 2000:688390, Iggo et al (WO 00/56909) discloses a protein sequence comprising a conservative variant of SEQ ID NO:15 as indicated by the underlined area,
- i. Database Caplus on STN, Accession Number 1995:28511, Parker et al (Gene, 1994, Vol. 145, pp. 135-138) discloses a protein sequence comprising a conservative variant of SEQ ID NO:16 as indicated by the underlined area,
- j. Database Caplus on STN, Accession Number 1999:9856, Madura (WO 98/57978) discloses a protein sequence comprising a conservative variant of SEQ ID NO:19 as indicated by the underlined area,

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k. Database Caplus on STN, Accession Number 2000:227762, Acton et al (WO 00/18899) discloses a protein sequence comprising a conservative variant of SEQ ID NO:21 as indicated by the underlined area,

l. Database Caplus on STN, Accession Number 1999:126776, Schatz (US 5,874,239) discloses a protein sequence comprising a conservative variant of SEQ ID NO:22 as indicated by the underlined area,

m. Database Caplus on STN, Accession Number 1998:267798, Wang et al (FEBS Letters, 1998, Vol. 427, pp. 103-108) discloses a protein sequence comprising a conservative variant of SEQ ID NO:27 as indicated by the underlined area,

n. Database Caplus on STN, Accession Number 1998:26477, Hanada et al (Journal of Biological Chemistry, 1997, Vol. 272, pp. 32108-32114) discloses a protein sequence comprising a conservative variant of SEQ ID NO:28 as indicated by the underlined area,

o. Database Caplus on STN, Accession Number 1999:60870, Jacobs et al (Clinical and Diagnostic Laboratory Immunology, 1999, Vol. 6, pp. 24-29) discloses a protein sequence comprising a conservative variant of SEQ ID NO:29 as indicated by the underlined area,

p. Database Caplus on STN, Accession Number 1999:66315, Kool et al (Cancer Research, 1999, Vol. 59, pp. 175-182) discloses a protein sequence comprising a conservative variant of SEQ ID NO:30 as indicated by the underlined area,

wherein each reference rejects claims 52 and 53 for the same reasons of record as in the prior office action.

The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the polypeptides of the prior art do not possess the same material, structural and functional characteristics of the claimed polypeptides. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed products are different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claims 39-43 and 45 are rejected under 102(b) as being anticipated by Renschler et al (WO 94/18345).

Claim 39 is drawn in part to an isolated peptide comprising a binding regions which preferentially binds to the surface of a cancerous blood cell and does not bind to a non-cancerous blood cell, wherein the peptide does not bind a tumor-specific antigen. Claim 40 embodies the method of claim 39 wherein the blood cell is a leukemia cell. Claim 41 embodies the polypeptide of claim 39, wherein the polypeptide comprises part of a carrier protein. Claim 42 embodies the polypeptide of claim 39, wherein the polypeptide comprises an accessory molecule. Claim 43 embodies the peptide of claim 42 wherein the accessory molecule is a tag molecule, chemotherapeutic agent, radiopharmaceutical, cytotoxic agent, treatment molecule, antigenic molecule, antibody fragment or antibody. Claim 45 embodies the polypeptide of claim 40 wherein the polypeptide inhibits proliferation of the leukemia cell.

Renschler et al teach the biotinylated peptide 3T802 conjugated to streptavidin, wherein said polypeptide binds to the B-cell surface immunoglobulins of B cell lymphocytic leukemia and inhibits proliferation thereby (Figure 2 and page 7, lines 5-6, and page 45, fifth table entry). The peptide would “comprise a part of a carrier protein” because a “part” can be read as a single amino acid. Streptavidin fulfills the specific embodiment of a “tag molecule” in claim 20. The B-cell surface immunoglobulin is not a tumor specific antigen, but a normal cell component which happens to be expressed by a clonal expansion of malignant B-cells.

All other rejections and objections as set forth in the previous action are withdrawn in light of applicants amendments.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

4/18/2005


KARENA CANELLA PH.D
PRIMARY EXAMINER